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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/798,799	03/10/2004	Arpita I. Mehta	4239-67983-01	5611

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EXAMINER	
GROSS, CHRISTOPHER M	

ART UNIT	PAPER NUMBER
1639	

DATE MAILED: 10/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/798,799	MEHTA ET AL.	
	Examiner	Art Unit	
	Christopher M. Gross	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 January 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-50* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-50* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-50 are pending.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-45, drawn to a method for selecting a combination of therapeutic agents, classifiable in class 435, subclass 4.

II. Claim 46-50, drawn to a method of treating a subject, classifiable in class 424, subclass 9.2.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are directed to related processes. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed have materially different mode of operation in that invention II is involves clinical studies and pathology which are not required in performing the method of invention I. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Species Election

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Each genus identified below is indicated in **bold.** Applicant is requested to elect one species from within *each* genus of the elected invention, from which the search will commence.

This application contains claims directed to the following patentably distinct species:

(From claims 3-6) **cell isolation technique**: microdissection, laser capture microdissection, or FACS. Currently, claims 1,3-6 are generic.

The species are independent or distinct because they involve materially different procedural steps.

(From claims 10-13) **activity state measurement technique**: protein microarray analysis, immunohistochemistry, antibody microarray analysis, bead capture, or reversed phase protein microarray analysis. Currently, claims 1,10-13 are generic.

The species are independent or distinct because they involve materially different biochemical procedures.

(From claims 14-16) **reference cell:** a normal cell, a cell before or after a treatment, a cell before or after a disease or a stage of disease, or a cell that has not been treated with a therapeutic agent. Currently claims 1,14-16 are generic.

The species are independent or distinct because each reference cell comes from a different source, each source requiring materially different procedures to prepare and/or maintain.

(From claims 17-19) **reference cell source:** same subject, another subject, or cultured cells. Currently claims 1,17-19 are generic

The species are independent or distinct because each source requires materially different procedures to prepare and/or maintain.

(From claim 21) **aberrant celluar response comprising**: abnormal growth, apoptosis, cytoskeletal remodeling, survival, receptor localization and distribution, gene transcription, motility, differentiation, proliferation, or angiogenesis. Currently claims 1 and 21 are generic.

The species are independent or distinct because they involve materially different cytological procedures.

(From claims 22-23) **measured activity:** protein-protein interaction, a post-translational modification, a protein cleavage, a translocation to an organelle or compartment, an ion channel activation, a concentration of a soluble mediator that is a product or a substrate of the protein, a protein-nucleic acid interaction, a protein-lipid

interaction, protein-carbohydrate interaction, phosphorylation, farnesylation, myristylation, acetylation, or ubiquitinization. Currently claims 1,22-23 are generic.

These species are independent or distinct because assessment involves materially different biochemical procedures.

(From claim 26) Applicant is requested to elect **two therapeutic targets** selected from the group consisting of: EGFr dimerization, EGFr phosphorylation, AKT phosphorylation, non-voltage gated calcium ion channels, cyclooxygenase-1, cyclooxygenase-2, MEK-1, NFKB/IKB, and P38. Currently claims 1 and 26 are generic.

These species are independent or distinct because assessment involves materially different biochemical procedures.

(From claims 30-35) Applicant is requested to elect **two (combination) therapeutics comprising**: Cal, specific Cox-2 inhibitor, Rofecoxib, Celecoxib or LM-1685, AKT kinase inhibitor, EGFR dimerization inhibitor, EGF kinase inhibitor, herceptin, IRESSA, PKCalpha agonist, or herceptin. Currently claims 1,31-35 are generic.

These species are independent or distinct because they do not share a common structural core.

(From claim 38) **signaling pathway:** ntegrin pathway, a focal adhesion signaling pathway, an Akt signaling pathway, an IL-6R pathway, a growth factor pathway, a chemokine receptor signal pathway, a cell-cycle signaling pathway, a stress signal pathway, an apotosis signaling pathway, a Tau/beta signaling pathway, a pro-inflammatory pathway, a differentiation signaling pathway, a T-cell receptor pathway, a

death-receptor signaling pathway, a survival signaling pathway, a MAPK signaling pathway, a p38 MAPK signaling pathway, a G-coupled Receptor signaling pathway, a SAPK/JNK signaling pathway, an insulin receptor signaling pathway, a Wnt signaling pathway, a c-Kit pathway, a c-kit signaling pathway, a B-cell antigen signaling pathway, or a Jak/Stat signaling pathway. Currently claims 1 and 38 are generic.

These species are independent or distinct because assessment involves materially different biochemical procedures.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species and invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher M. Gross whose telephone number is (571)272-4446. The examiner can normally be reached on M-F 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on 571 272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Christopher M Gross

MARK SHIBUYA, PH.D.
PATENT EXAMINER

Examiner
Art Unit 1639

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